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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,659	05/05/2005	Masahiro Nishimura	270257US0XPCT	1362

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EXAMINER	
KAROL, JODY LYNN	

ART UNIT	PAPER NUMBER
1609	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/533,659	NISHIMURA ET AL.	
	Examiner	Art Unit	
	Jody L. Karol	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 8/2/2005.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-4 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-3 is/are rejected.

7)☒ Claim(s) 4 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 5/5/2005, 8/2/2005.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is a 371 of PCT/JP03/14251 International Filing Date: 11/10/2003, which claims priority to Japan 2002-326535. Claims 1-4 are pending and examined on the merits herein.

Information Disclosure Statement

1. The information disclosure statements (IDS) filed on 5/5/2005 and 8/2/2005 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority based on Application No. 2002-326535 filed in Japan on 11/11/2002.

Specification

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: A Composition for Restoring Damage Skin Comprising a Saccharide and Povidone-Iodine.

4. The abstract of the disclosure is objected to because the abstract is more than one paragraph, and the language is not clear in that it does not conform to idiomatic English. Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

5. A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. The substitute specification filed must be accompanied by a statement that it contains no new matter.

6. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.

(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

7. The use of several trademarks, such as COATSOME® NC-50, Lecinol® S-10, and Marcrogel® 300, have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

8. Claim 4 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim **cannot depend from any other multiple dependent claim.**

See MPEP § 608.01(n). Accordingly, the claim 4 has not been further treated on the merits.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 5,618,799 in view of Fleischer et al. (WO 99/60998) published 12/2/1999. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a wound healing composition comprising a saccharide, povidone-iodine, water, and a phospholipid, where the patent claims are drawn to a wound healing composition consisting essentially of a sucrose, povidone-iodine powder, and a water soluble polymer wherein the composition is a powder.

The patented claims do not indicate that water or phospholipids are present in the composition. However, phospholipids such as lecithin have been used in liposome preparations containing povidone-iodine. Fleischer et al. teaches liposome preparations containing povidone-iodine for the local treatment of infections of the nose, mouth, and throat (see page 11, lines 8-10). Fleischer et al. further discloses lotions, ointments, and hydrogels that contain the liposomes and water (see page 13). The liposomes mentioned include phospholipids, such as hydrogenated soybean lecithin (see page 13, lines 5-6). Fleischer et al. also teaches that the liposome preparations can be dispersed in a sugar electrolyte solution (see page 15, lines 17-19). Therefore, it would be obvious to one of ordinary skill in the art that phospholipids and water could be added to the composition of the patented claims to create liposome preparations for the treatment of local infections. Accordingly, the instant claims 1-3 are obvious over the patented claims in view of Fleischer et al. (WO 99/60998), and thus are not patentably distinct over the US 5,618,799 patent.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by European Patent Application No. 1 224 937 A1, published 7/24/2002 (Hara et al.).

Claim 1 is directed to a composition for repairing injured skin comprising 50 to 90% by weight of a saccharide, 0.5 to 10% by weight of povidone-iodine, 0.1 to 20% by weight water, and 0.1 to 10% by weight of phospholipid. Claim 2 specifies that the saccharide is white soft sugar. Claim 3 specifies that the composition of claim 1 or 2 contain a phospholipid that is a natural phospholipid or a hydrogenated phospholipid. The term "comprising" is interpreted to be broad and open-ended.

Hara et al. teaches a formulation for the use of treating wounds or bedsores that comprises a sugar (saccharide) in 50 to 90% by weight, povidone-iodine in 0.5 to 10% weight, and gelatin in 0.5 to 20% by weight (see abstract and page 3, lines 45-50). Hara et al. also discloses that water may or may not be present, and that an emulsifier such as hydrogenated lecithin may be present in amounts less than 40% by weight (page 3, lines 53-53, page 4, lines 4-8, and the examples, specifically example 2). Sucrose, a white soft sugar, is one of the preferred sugars utilized (see page 3, lines 42-44). Therefore, all the limitations of claims 1-3 are met.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Komori et al. (US 4,884,898) in view of Ogawa et al. (US 6,130,329).

The instant claims are directed to wound healing compositions as described above.

Komori et al. teaches wound healing compositions comprising 50 to 90% by weight of a sugar (saccharide), 0.5 to 10% by weight of povidone-iodine, and 1-20% by weight of water (see abstract). Sucrose, a white soft sugar, is an example of one of the sugar utilized (see column 2, lines 64-end). However, Komori et al. does not disclose any embodiments where a phospholipid is present.

Ogawa et al. teaches that by adding a lecithin compound, such as lecithin from egg yolk or lysolecithin, to an aqueous solution of a sucrose fatty acid, the viscosity is lowered (see column 3, lines 47-63). Lecithin is noted as an anionic surface active agent, and they are used in 0.1-9% by weight of the composition (see column 5, lines 35-45). Ogawa et al. also discloses that by reducing the viscosity of the aqueous solution, the preservation and workability were improved (see column 2, lines 40-47). The composition taught by Ogawa et al. can be used in pharmaceuticals such as those for antibacterial treatment (see column 1, lines 23-43).

Therefore, it would be obvious to one of ordinary skill in the art to add a phospholipid to an aqueous solution as taught in Ogawa et al., to decrease the viscosity and thereby improve the storage and ease of processing of the wound healing aqueous composition of Komori et al., and since both references each teach that their compositions can be used as pharmaceuticals, i.e. antibacterial and wound healing treatments.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Conclusion

No claims are allowed.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jody L. Karol whose telephone number is (571) 274-3283. The examiner can normally be reached on 8:30 am - 5:00 pm Mon-Fri EST.

JLK Jody Karol

MICHAEL MELLER
PRIMARY EXAMINER